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JUN 19 2009

MAKO SURGICAL CORP.

2555 davie road fort lauderdale, florida 33317 tel 954.927.2044 fax 954.927.0446

EXHIBIT 9
510(K) SUMMARY

Submitter:	MAKO Surgical Corp.
Address:	2555 Davie Road, Fort Lauderdale, FL, 33317
Phone number:	954-927-2044 x 605
Fax number:	954-927-0446
Contact Person:	William F. Tapia
Date Prepared:	December 5, 2008
Device Trade Name:	Tactile Guidance System – Hip (TGS – Hip)
Regulation Number:	21 CFR 882.4560
Regulation Name:	Stereotaxic Instrument
Regulatory Class:	Class II
Product Code:	HAW

Substantial Equivalence Claimed To: The TGS – Hip is substantially equivalent to MAKO Surgical's Tactile Guidance System (K072806), Brainlab's Vectorvision Hip (K010602, K040368, K052213, K072716) and Orthosoft's Navitrack System – Total Hip Replacement (K022364).

Description: The TGS – Hip is a stereotaxic instrument that includes an optical detector, computer, dedicated instrumentation, operating software, tools and accessories, and a robotic arm. The TGS – Hip is enabled for use in conjunction with a 3rd party drill system (e.g., Stryker drill system) in order to support the surgeon's preparation of the acetabulum during total hip arthroplasty. The TGS – Hip uses patient CT data to assist the physician with presurgical planning and interpretive/intraoperative navigation. The TGS – Hip robotic arm serves as an "intelligent" tool holder or tool guide used by a surgeon for stereotactic guidance during minimally invasive orthopedic surgical procedures. The TGS - Hip robotic arm, an electromechanical arm, is passively constrained by software-defined spatial boundaries implemented through the use of the robotic arm and is designed to support a surgeon's preparation of an anatomical site for an orthopedic implant with standard surgical tools such as burrs and reamers.

Summary of Technological Characteristics Compared to Predicate Devices:
The technological characteristics of the TGS-Hip compared to the predicate devices is listed below:

Technological Characteristics	TGS-Hip	Brainlab Vectorvision (VV) Hip	Orthosoft Navitrack System – Total Hip Replacement
Major Components	Guidance Module, robotic arm, camera stand	Available in several different configurations (VV-Compact, VV-Sky, VV-2)	Computer cart, camera stand
Tools/accessories	Various probes, arrays tracked by optical camera	Various probes, arrays tracked by optical camera	Various probes, arrays tracked by optical camera
Images Use	CT	CT, CT-free	CT

Performance Data:
System level verification testing was performed in the laboratory with TGS-Hip using sawbone models to evaluate setup, registration, and overall accuracy and functionality of the system in supporting acetabular reaming during THA. Further testing was performed with TGS-Hip using cadaveric material where post-operative x-rays/CT scans were obtained and evaluated in order to validate the system's intended use. The results of these tests satisfied all required acceptance criteria and were found to support substantial equivalence of the TGS-Hip to the predicate devices.

Intended Use/Indications for Use: The Tactile Guidance System - Hip is intended to assist the surgeon in providing software defined spatial boundaries for orientation and reference information to anatomical

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structures during orthopedic procedures. The Tactile Guidance System - Hip is indicated for use in surgical hip procedures, in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be identified relative to a CT based model of the anatomy. These procedures include:

- Acetabular reaming during total hip arthoplasty (THA)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2009

Mako Surgical Corporation
% Mr. William F. Tapia
Director, Regulatory Affairs
2555 Davie Road
Davie, Florida 33317

Re: K083644
Trade/Device Name: Tactile Guidance System - Hip
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: OLO
Dated: May 28, 2009
Received: June 2, 2009

Dear Mr. Tapia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) Number (if known): K083644

Device Name: Tactile Guidance System - Hip

Indications for Use:

The Tactile Guidance System - Hip is intended to assist the surgeon in providing software defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures.

The Tactile Guidance System - Hip is indicated for use in surgical hip procedures, in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be identified relative to a CT based model of the anatomy. These procedures include:

- Acetabular reaming during total hip arthoplasty (THA)

Prescription Use ___X___ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Kroger for mkm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083644